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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/698,095      | 10/31/2003  | William J. Bertrand  | P-11490.00          | 1017             |

27581 7590 10/05/2006

MEDTRONIC, INC.  
710 MEDTRONIC PARK  
MINNEAPOLIS, MN 55432-9924

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| EXAMINER |
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LUSTUSKY, SARA

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| ART UNIT | PAPER NUMBER |
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3735

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |  |
|------------------------------|-----------------|-----------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |  |
|                              | 10/698,095      | BERTRAND ET AL. |  |
|                              | Examiner        | Art Unit        |  |
|                              | Sara Lustusky   | 3735            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/03</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (18) as seen in Figure 1, (20) (22) (24) (68) as seen in Figure 2, (800) as seen in Figure 8, and (900) as seen in Figure 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

**Claims 10, 21, 25 and 30** are objected to because of the following informalities:

In line 2 of claim 10 - - the- - should be inserted between "while" and "magnetic".

Claim 21 is a duplicate of claim 11 and therefore the examiner presumes the recitation "according to claim 1" in line 1 should read - - according to claim 16 - -.

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Claim 25 is a duplicate of claim 15 and therefore the examiner presumes the recitation "according to claim 14" in line 1 should read - - according to claim 21- -.

In line 2 of claim 30, the recitation "sensor" should read - - sensors - -.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-15, 23 and 25** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the language in claim 1 whether the "valve" (recited in line 7) is positively claimed.

The recitation "corresponds to a particular model corresponding to", in line 3 of claim 13 and in line 2 of claim 23, does not indicate what kind of model is being claimed and it is unclear if the model is a type of data stream, a type of software program, a type of implantable device, etc.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3** are rejected under 35 U.S.C. 102(b) as being anticipated by Golden et al. (Patent 5425382).

Golden et al. teaches an electronic magnetic-based indicator tool comprising: a housing having an electronic display (as described in lines 16-22 of column 4); a plurality of magnetic field sensors grouped into sets to determine the location and orientation of a magnetic device (as described in lines 45-62 of column 6); and a processing module for receiving magnetic data values from the magnetic field sensors (as described in lines 12-24 of column 8) (as seen in Figure 1A); the device being capable of determining a setting for a valve on an implantable flow control device as it determines the orientation of a magnetic device (as seen in Figures 3 and 4) wherein this may be determined based on a reference magnet on an implanted device (as described in lines 54-68 of column 7 and lines 1-11 of column 8).

**Claims 1, 4-7, 11, 13-14, 25-30** are rejected under 35 U.S.C. 102(b) as being anticipated by Haynor et al. (Patent 6129668).

Haynor et al. teaches an electronic magnetic-based indicator tool and method of using the tool comprising a housing having an electronic display; a plurality of magnetic field sensors grouped into sets; and a processing module for receiving magnetic data values from the plurality of magnetic field sensors making it capable of determining a setting for a valve on an implantable flow control device wherein the plurality of magnetic field sensors may comprise four sets of three sensors (as described in lines 2-10 and lines 23-28 of the abstract; in lines 52-59 of column 2; and in claim 35); wherein

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the indicator tool is positioned over an estimated location of the implanted magnetic device; wherein the magnetic field sensors may be Hall-effect sensors (as described in lines 26-29 of column 3) for determining location and orientation of a magnetic device for the x, y and z axis and for theta and phi (as described in lines 53-60 of column 5; in lines 56-58 of column 6; in lines 6-10 and 14-28 of column 7), therefore the orientation is determined in five degrees of freedom; wherein the sets of sensors may be located about a respective one of four corners of the indicator tool (as seen in Figures 3-4 and 8A-D); wherein the processing module determines an estimate for ambient magnetic fields from a sequence of magnetic data values and subtracts the estimate from received magnetic data values to determine the location and orientation of only the field of the implanted magnetic device (as described in lines 40-45 and 54-57 of column 3; and in lines 57-60 of column 4); wherein the user operated tool further comprises a removable data storage device (170) containing computer readable data capable of being used to translate a valve setting into pressure for an implantable flow control device (as seen in Figures 5A-B); wherein the computer readable data corresponds to a particular model of software which is capable of detecting the location and orientation of the desired magnetic device (as described in lines 5-9 of column 22).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 4 and 5** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Golden et al. (Patent 5425382) as applied to claim 1 above.

Golden et al. teaches an electronic magnetic-base indicator tool comprising a housing, a plurality of magnetic field sensors and a processing module, as described above.

Golden et al. does not expressly teach that the ambient magnetic fields are estimated as a received sensed magnetic value (other than zero) to be subtracted from the received sensed magnetic data values.

Instead, Golden et al. teaches that the ambient magnetic fields from the earth are estimated as zero with respect to the sensed magnetic data and is rendered null because of the way the sensed magnetic data is compared; therefore they are removed or theoretically subtracted from the data acquired to determine the location and orientation of a magnetic device (as described in lines 21-31 of column 3, and in lines 45-62 of column 6).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to negate the need to sense and subsequently subtract the estimated ambient magnetic fields from the sensed magnetic data because Applicant has not disclosed that sensing and subsequently subtracting the estimated ambient magnetic fields provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would

have expected Golden et al.'s tool, and applicant's invention, to perform equally well because both devices ultimately use sensed magnetic data only for the magnetic field emitted by the magnetic device and not the ambient magnetic field to determine a location and orientation.

Therefore, it would have been prima facie obvious to modify Golden et al. to obtain the invention as specified in claims 4 and 5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Golden et al..

**Claims 8-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Golden et al. (Patent 5425382) as applied to claim 1 above, in view of Ito (PGPUB 2001/0022350 A1).

Golden et al. teaches an electronic magnetic-base indicator tool comprising a housing, a plurality of magnetic field sensors and a processing module, as described above. However, while the tool of Golden et al. is capable of detecting a magnetic object on a valve, it is not taught that the device is used with an adjusting tool for modifying the orientation of a valve based on the sensed data.

Ito teaches an adjustment tool for use with an implanted flow control device comprising a valve; wherein the adjustment tool modifies the orientation of the implanted valve. Ito further teaches that adjustments to the valve are made only after the initial orientation of the valve is determined using an MRI apparatus to magnetically sense the position and orientation of a magnetic indicator device on the flow control device, which by design is the only magnetic part of the implant; wherein the adjustment



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tool comprises a magnetic adjustment component for magnetically coupling to the magnetic indicator device of the flow control device; wherein rotating the adjustment tool while the magnetic adjustment component while magnetically coupled to the magnetic indicator device changes the setting of the valve by rotation (as described in paragraphs [0026] - [0028]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a device similar to that of Golden et al. to sense the position and orientation of a valve similar to that of Ito and therefore used in combination with an adjustment tool similar to that of Ito because the device of Golden et al. is much smaller than an MRI apparatus and can be used by a doctor and therefore eliminates the time and resources used by scheduling and receiving an MRI.

**Claim 15** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haynor et al. (Patent 6129668) as applied to claims 1 and 14 above.

Haynor et al. teaches an electronic magnetic-based indicator tool and method of using the tool comprising a housing having an electronic display; a plurality of magnetic field sensors grouped into sets; and a processing module for receiving magnetic data values from the plurality of magnetic field sensors making it capable of determining a setting for a valve on an implantable flow control device wherein in one embodiment the tool is a handheld device containing the magnetic sensors and associated electronics which require power (as described in lines 2-5 of column 22). However, Haynor et al.

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does not expressly teach the use of batteries as a power supply. It would have been obvious to one of ordinary skill in the art at the time of the invention to use batteries as a portable power supply with the device.

**Claims 16-21, and 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynor et al. (Patent 6129668) in view of Ito (PGPUB 2001/0022350 A1).

Haynor et al. teaches an electronic magnetic-based indicator tool comprising a housing having an electronic display; a plurality of magnetic field sensors grouped into sets; and a processing module for receiving magnetic data values from the plurality of magnetic field sensors making it capable of determining a setting for a valve on an implantable flow control device (as described in the abstract and in lines 2-10 and lines 23-28 of the abstract; in lines 52-59 of column 2); wherein the processing module generates a display image corresponding to the orientation of the magnetic device and outputs the display image on an electronic display; wherein the processing module determines an estimate for ambient magnetic fields from a sequence of magnetic data values and subtracts the estimate from received magnetic data values to determine the location and orientation of only the field of the implanted magnetic device (as described in lines 32-45 and 54-57 of column 3; and in lines 57-60 of column 4); wherein the tool further comprises a removable data storage device (170) containing computer readable data capable of being used to translate a valve setting into pressure for an implantable flow control device (as seen in Figures 5A-B); wherein in one embodiment the tool is a

handheld device containing the magnetic sensors and associated electronics which require power and would have therefore been obvious to one of ordinary skill in the art at the time of the invention to use batteries with the device (as described in lines 2-5 of column 22); wherein the computer readable data corresponds to a particular model of software which is capable of detecting the location and orientation of the desired magnetic device (as described in lines 5-9 of column 22).

However, while the tool of Haynor et al. is capable of detecting a magnetic object on a valve, it is not taught that the device is used with an adjusting tool for modifying the orientation of a valve based on the sensed data.

Ito teaches an adjustment tool for use with an implanted flow control device comprising a valve; wherein the adjustment tool modifies the orientation of the implanted valve. Ito further teaches that adjustments to the valve are made only after the initial orientation of the valve is determined using an MRI apparatus to magnetically sense the position and orientation of a magnetic indicator device on the flow control device, which by design is the only magnetic part of the implant; wherein the adjustment tool comprises a magnetic adjustment component for magnetically coupling to the magnetic indicator device of the flow control device; wherein rotating the adjustment tool using user controls while the magnetic adjustment component is magnetically coupled to the magnetic indicator device, changes the setting of the valve by rotation (as described in paragraphs [0026] - [0028]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a device similar to that of Haynor et al. to sense the position and

orientation of a valve similar to that of Ito and therefore used in combination with an adjustment tool similar to that of Ito because the device of Haynor et al. is much smaller than the common MRI apparatus, which often encompasses an entire room, and can be used by a doctor in their office and therefore eliminates the time and resources used by scheduling and receiving an MRI.

**Claims 12 and 21-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynor et al. (Patent 6129668) for claim 12 and the combination of Haynor et al. (Patent 6129668) and Ito (PGPUB 2001/0022350 A1) for claims 21-22, in view of Drinan et al. (PGPUB 2003/0004403 A1).

Haynor et al. teaches an electronic magnetic-based indicator tool comprising a housing having an electronic display; a plurality of magnetic field sensors grouped into sets; and a processing module as part of a computer, as described above. Haynor et al. teaches the use of internal memory within the computer and the use of a recorder to save the images created from the output data on the visual display but does not teach the use of a removable data storage consisting of flash memory or a compact flash memory device.

Drinan et al. teaches a tool for remote monitoring of an implant within a human body comprising a handheld detector and a computer (as described by the abstract and as seen in Figures 1-2). Drinan et al. further teaches the use of flash memory and a compact flash memory device (as described in claims 1, 33 and 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to save the sensed and processed data from a tool similar to that of Haynor et al. with flash memory or a compact flash memory device similar to that taught by Drinan et al. because this is an affordable and easy way to transport the medical data between different doctor's computers and a way to create an archive other than the information saved on the computer.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen (Patent 4622644) teaches the use of magnetic field sensors to determine the position and orientation of magnetic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

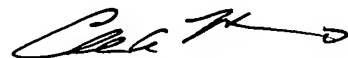
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S.L.

Charles A. Marmor, II  
SPE, Art Unit 3735